

Radiation Safety Committee	Non-Routine Use Protocol Review
Standard Operating Procedure	

Background	The Radiation Safety Committee (RSC) is required to review and approve all uses of radioactive materials or human exposure to ionizing radiation that are not routine and cannot be delegated for review and approval by the Radiation Safety Staff. Examples of such uses are human studies, field applications, large-animal studies (animals > 5 kg), and syntheses of materials using large quantities of isotopes. The RSC has established a Human and Non-Routine Protocol Review Subcommittee whose members have appropriate technical expertise to review these protocols and make recommendations on approval to the RSC.
Program Authorities and Approvals	<p>USDA Radiation Safety Committee: The RSC is authorized to approve the use of ionizing radiation or radioactive materials. Review by the RSC is limited to-compliance with the USDA's broad scope license requirements. This review is not a technical evaluation of radiation dose to workers or members of the public or an assessment of the appropriateness of the non-routine use protocol.</p> <p>Human and Non-Routine Protocol Review Subcommittee: The RSC has established this Subcommittee to review Human and non-routine use protocols and to make approval recommendations to the RSC. This committee is composed of the USDA Radiation Safety Officer; Chair of the RSC; and Technical Representatives for Animal, Human, and Biotechnology Research. Review by this Subcommittee is limited to compliance with the USDA's broad scope license requirements. This review is not a technical evaluation of radiation dose to human subjects or an assessment of the appropriateness of the human use protocol.</p> <p>USDA Radiation Safety Staff: The RSS is responsible for reviewing Protocols to ensure adequate dose evaluations are made and adequate radioactive materials control and security procedures will be followed.</p>
USDA Authorities and Approvals	Agency: Agency representatives (Research Leaders, Center Directors, Area Directors, or other appropriate management) must approve the use of radioactive materials in non-routine use protocols submitted to the RSC for review. The permit holder must provide documentation that an agency management representative has approved such use (e-mail correspondence or fax of documentation is sufficient).

Non-USDA Authorities and Approvals	Formal approval from Federal or State regulatory agencies, such as the NRC and the Environmental Protection Agency, may be required. The permit holder and (or) RSS must obtain appropriate approvals.
Protocol Review Process	<ol style="list-style-type: none"> 1. <u>Permit Holder</u> <ul style="list-style-type: none"> • obtains approval from agency management representative • obtains approval from regulatory agency (if necessary) • submits the protocol and approvals to the RSS 2. <u>Radiation Safety Staff</u> <ul style="list-style-type: none"> • obtains all safety information or approval documentation (if needed) • obtains approval from regulatory agency • sends protocol and other relevant documentation to the Human and Non-Routine Protocol Review Subcommittee 3. <u>Human and Non-Routine Protocol Review Subcommittee</u> <ul style="list-style-type: none"> • Members review the protocol • Members send a signed approval form to RSS 4. <u>Radiation Safety Staff</u> <ul style="list-style-type: none"> • sends a letter to the permit holder indicating whether the Subcommittee approved the protocol • amends the permit to include approved protocol materials and documents

Approved: <hr/> Chair, Radiation Safety Committee	<hr/> Date
--	------------